

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

19/5

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/012528

International filing date (day/month/year)
05.11.2004

Priority date (day/month/year)
07.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61M1/36, A61M1/16

Applicant
GAMBRO LUNDIA AB

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012528

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012528

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-38
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-38
Industrial applicability (IA)	Yes: Claims	1-38
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

1 Reference is made to the following documents:

D1 : US 4 231 871 A (LIPPS BENNIE J ET AL) 4 November 1980 (1980-11-04)

D2 : EP 0 292 445 A (SORIN BIOMEDICA S.P.A) 23 November 1988 (1988-11-23)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.

2.1.1 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (see column 7, figures 10 and 11, the references in parentheses applying to this document):

2.2.2 An integrated blood treatment module comprising:

- a blood treatment device (177) having:
- a housing having a longitudinal axis ;
- a first end-cap closing a first end of the housing, the first end-cap having a blood inlet port;
- a second end-cap closing a second end of the housing;
- a pump hose for a peristaltic pump (186), wherein the pump hose has a first end that is secured to the filter and a second end that is connected to the blood inlet port (145) so that the pump hose extends in a position that is complementary to the position of a race of the peristaltic pump; and
- a degassing device connected to the second end-cap having:
- a first chamber (124) having an inlet for receiving a liquid flowing into the second end-cap ,
- a second chamber (158) having an opening (156) closed by a hydrophobic membrane, and an outlet for discharging the liquid.

2.1.2 The subject-matter of independent claim 1 differs from the disclosure of D1 in that :

The first chamber has a downstream portion that partially extends within the second chamber and communicates therewith by a passageway, and the second chamber has a downstream portion that extends below the passageway and asymmetrically

surrounds the downstream portion of the first chamber.

2.1.3 The problem to be solved by the present invention may therefore be regarded as providing an effective degassing chamber.

2.1.4 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) because the same solution was adopted in D2 to solve the same problem (see abstract and figure

2.1.5 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

3 DEPENDENT CLAIMS 2-38

Dependent claims 2-38 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). See the relevant documents in the search report.

Re Item VIII.

1.1 The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear. Reasons are as follows:

- The blood treatment module of claim 1 comprises a pump hose and
- ***The pump hose extends in a position that is complementary to the position of a race of the peristaltic pump*** (see line 16), but the peristaltic pump is not included in the intended scope of protection. It is thus not clear what limitation is implied by this statement. Even if a more precise description of the pump would be included, the expression ***so that the pump hose extends in a position that is complementary to the position of a race of the peristaltic pump*** would still represent a result to be achieved, instead of a clear technical feature of the device. This can be illustrated by the observation that this result is always achieved once a disposable set for dialysis comprising a filter and a pump hose has been positioned on the dialysis machine.

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

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- The term ***asymmetrically surrounds*** used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature/s to which it refers.
- The term ***below*** is used without any explanatory definition of the relative positions of the elements of the device